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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,118

04/26/2006

Arthur W. Crossman

101-04

4316

7590

03/01/2010

Robert J Decker
2679 Teakwood Drive
Charlottesville, VA 22911

EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

03/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,118	Applicant(s) CROSSMAN, ARTHUR W.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/2009</u> . | 6) <input type="checkbox"/> Other: ____. |

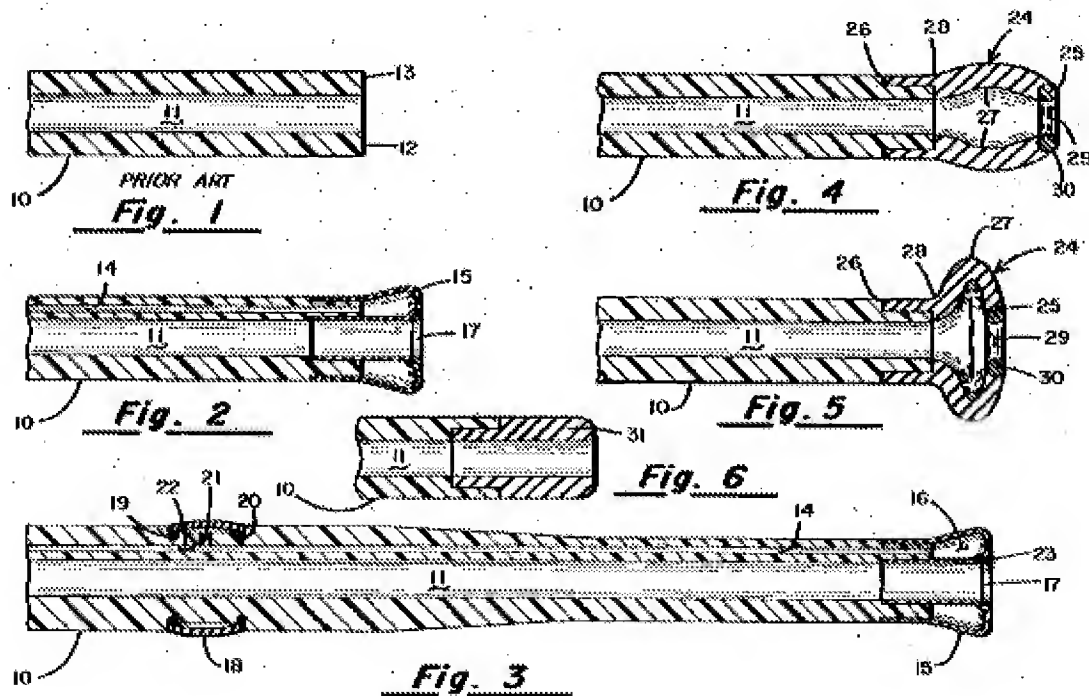
DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Tassel et al. (US 4,531,943; hereafter Van Tassel).



The Van Tassel patent shows in the figures above, a catheter shaft having a proximal portion and a distal portion, and a distal tip disposed on the distal portion, the distal tip having a blunt shape. In relation to claim 3, distal tip (13) is inflatable. In relation to claim 4, figure 4 shows an olive shape distal tip.

Claim Rejections - 35 USC § 103

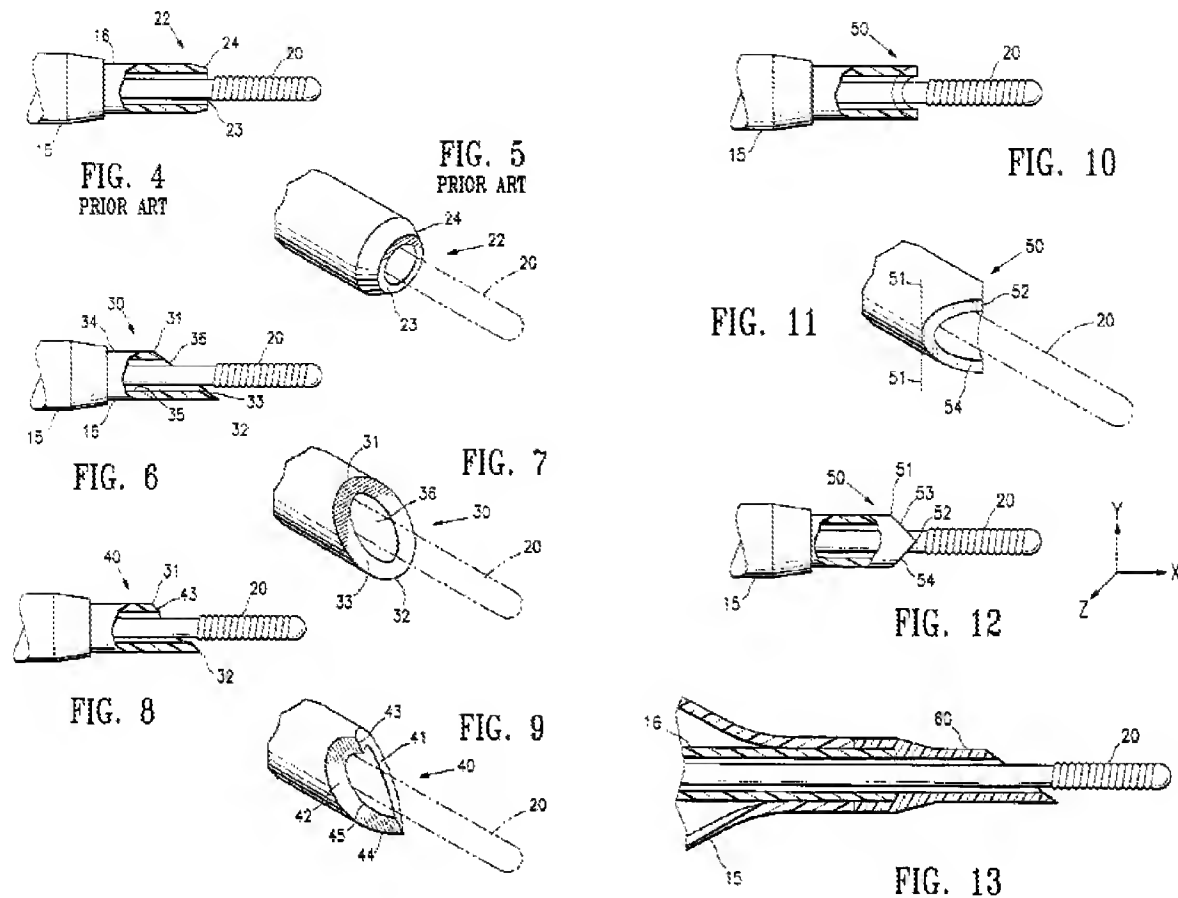
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Makower** et al. (US 5,290,310; hereafter Makower).

The Van Tassel patent does not disclose a sheath to introduce the catheter. However, the use of a sheath to introduce a catheter would have been considered conventional in the art as evidenced by the teachings of Makower. The Makower patent shows in figure 1, a sheath (40) use for the introduction of a catheter into the body. Based on the teachings of Makower, for a person of ordinary skill in the art, modifying the apparatus disclosed by Van Tassel with an introducer, as taught by Makower, would have been considered obvious in the art in view of the proven conventionality of catheter introducer/sheath, and moreover, because catheter sheath use to introduce catheters facilitate the deployment and removal of medical instruments during medical procedures.

Claims 5-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852).



As stated in the previous Section 102 rejection, Van Tassel discloses a set-back extension having an olive shape (claim 14). In the figures above, the Lee patent shows a set-back extension (claim 5), blunt shapes to avoid trauma (claim 6), a tapered set-back extension (claim 7), a set-back extension having a semi-elliptical shape (claims 8, 15, 19, 20), a tip that can be manipulated and that is blunt to avoid trauma (claims 9, 16, 17, 18), a balloon that is inflatable with a pre-formed shape (claims 10, 11, 21), an extension located on the distal end of the distal tip (claim 12), and blunt shapes to mitigate trauma (claim 13).

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Based on the above observations, for a person of ordinary skill in the art, modifying the Van Tassel catheter with the enhancements discussed above, would have been considered obvious in the art in view of the proven conventionality of these enhancements, and moreover, because the implementation of these enhancements in the catheter disclosed by Van Tassel would have reduce trauma in patients during surgical procedures.

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3983879), **Valley et al.** (US 5,814,016), or **Menasche** (US 4,927,412).

Van Tassel discloses a balloon (18), but does not disclose all the balloon shapes claimed in this invention. However, the Todd patent discloses a spherical and rounded balloon, the Menasche patent discloses a conical balloon, and the Valley patent discloses oval and cylindrical balloon shapes.

Based on the above observations, for a person of ordinary skill in the art, modifying the Van Tassel patent with balloons of different shapes, as taught by Todd, Valley, and Menasche, would have been considered obvious in view of the proven conventionality of these particular balloon shapes, and moreover, because the claimed balloon shapes would have been considered obvious alternatives in the design process of the catheter at the time the invention was made.

Claims 29-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3983879), **Valley et al.** (US 5,814,016), or **Menasche** (US 4,927,412), and in further view of **Yoon** (US 5,613,950).

Van Tassel does disclose an embodiment having multiple balloons. The Yoon patent is presented in this rejection to demonstrate the conventionality of using multiple balloons in one catheter, and moreover, the use of balloons of different shapes. (See figure 11A).

In relation to claims 34-40, based on cited evidence, all the features of the claimed invention would have been known at the time the invention was made. Accordingly, absent any criticality, variations in size and/or dimensions of a well-known catheter and/or catheter features would have been considered obvious variations in the design process performed according to the intended use of the catheter system.

Claims 41-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3983879), **Valley et al.** (US 5,814,016), **Menasche** (US 4,927,412), or **Yoon** (US 5,613,950), and in further view of **Duane** et al. (US 6,800,065; hereafter Duane) or **Shturman** (US 4,770,653).

Van Tassel is silent about the intended uses recited in the cited claims. However, the Duane patent demonstrates the conventionality of using introducing catheters in to the heart via veins or arteries, and conducting angioplasty, PTA, and

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PTCA procedures. The Shturman patent demonstrates the conventionality of using catheters to perform laser angioplasty.

Based on the above observations, for a person of ordinary skill in the art, modifying the Van Tassel patent to perform the procedures disclosed above, as taught by Duane and Shturman, would have been considered obvious in view of the conventionality of these procedures, and moreover, because such modifications would have enhanced the efficiency of the catheter in question.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM